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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

EFFICACY REVIEW

Efficacy of Imidacloprid (NTN 33893) Solution Applied Dermally For Control of Fleas on Dogs

Date in: 6/26/95 Date out: 1/25/96

Reg. Numbers: 11556-RRT (117); RRO (119); REN (120); RER (121)

Pin Date: 6/7/95

Type of product: 10% solution

Study titles: "Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally For Control of Fleas on Dogs", Jerry Cunningham, 1995 and "Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally For Control of Fleas on Dogs", Jerry Cunningham and Ron Everett, 1994.

Product Manager: Dennis H. Edwards Jr.

Team Reviewer: Portia Jenkins

Efficacy Reviewer: Paul Schroeder

Product Name: imidacloprid; NTN 33893; Bayer t 7391

Trade Name: Not provided.

Company name: Miles Laboratory, Bayer Corporation

Submission purpose: Support registration of products containing imidacloprid to control fleas on dogs.

Chemical & formulation: Ten % imidacloprid was applied to the back skin of each dog to administer 0.1, or 0.2 mg ai/kg body weight. In the other study imidacloprid was applied at 0.375, 0.750, or 1.00 mg ai/kg body weight.

Claims Wanted: Control of fleas, with residual activity, on dogs.

Testing Laboratory: Agresearch Consultants, Inc., P.O. Box 390, Shawnee, KS 66201.

In one study, MRID 436796-09, 32 adult dogs were assigned to four groups of eight dogs each. Three groups were treated with Bay t 7391 (10% imidacloprid). The dogs in group 1 were treated at the rate of 3.75 mg/kg bw. The dogs in group 2 were treated at the rate of 7.50 mg/kg bw. The dogs in group 3 were treated at the rate of 10.mg/kg bw. The dogs in the fourth group were treated with blank vehicle. All treatments were applied with a syringe to the skin surface on the back between the shoulder blades.

The dogs were observed at 30 minutes and 1, 3, and 5 hours and daily thereafter for the duration of the test for signs of adverse effects.

Each dog was infested with approximately 100 adult fleas one day before and 6, 13, 20, 27, and 33 days after treatment. The fleas on each dog were visually counted 1, 7, 14, 21, and 28 days after treatment. The fleas were combed out of the dogs fur and counted 34 days after treatment.

All three treatments gave good control of adult fleas for the study (34 days). It was noted that control was only partial for a few individuals.

No adverse reactions of test animals were noted.

In another study, MRID 436796-10, 30 dogs were selected as suitable flea hosts for use in a laboratory test. Each dog was infested with 100 unfed adult fleas from the laboratory colony two days before treatment and 6, 13, 20, 27, 34, and 41 days after treatment. The dogs were examined for surviving fleas 1, 7, 14, 21, and 28 days after treatment. The dogs fur was combed and fleas removed 1 day before treatment, 35 days after treatment and 42 days after treatment.

All dogs were examined 30 minutes, 1, 3, and 5 hours after treatment for any evidence of reaction to the insecticide. Observations were continued on a daily basis during the study to monitor the health status of each dog.

Treatments were as follows:

1. 8.5% w/w NTN solution, 0.1 ml/kg body weight
2. 5.0% w/w NTN solution, 0.2 ml/kg body weight
3. Control - Treatment with blank vehicle at 0.2 ml/kg body weight

Group 1 received the solution at one location on the skin between the shoulder blades. Group 2 received 1/2 of the solution between the shoulder blades and 1/2 on the top of the rump.

The results indicated complete (100%) control of cat fleas by treatment with 5.0% w/w NTN solution (0.2 mg/kg bw) for

at least the first week. Flea control was 93% or greater in this group for the first five weeks.

Flea control in the group treated with 0.1 ml 8.5% solution/kg b.w. was 99.7% at the end of the first week. Thirty five days after application this treatment afforded 94% control of adult cat fleas. The level of control was virtually the same for both treatments throughout the test.

There was little difference in efficacy between group 1 in which the solution was put in one location, (on the skin between the shoulder blades), and group 2 in which half the dose was applied to the skin between the shoulder blades and half was applied to the skin on top of the rump. There is no need to place the insecticide anywhere but in one location between the shoulder blades.

In contrast to results of tests with cats there was no evidence of adverse reactions of dogs to this chemical. This probably reflects the difference in grooming habits or may be the result of greater tolerance of imidacloprid by dogs.

Imidacloprid is effective against cat fleas on dogs for up to five weeks when placed along the top line.